IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC., and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant and Counter-Plaintiffs v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff and Counter-Defendants.	[redacted]

NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.'S OBJECTIONS TO SPECIAL MASTER ORDER NO. 1 DENYING MOTION TO COMPEL PRODUCTION OF LICENSE AGREEMENTS

Pursuant to Federal Rule of Civil Procedure 53(f) and Paragraph 6 of the Court's Order Appointing Special Master (D.I. 219), Plaintiff/Counter-Defendant Nippon Shinyaku Co. Ltd. and Counter-Defendant NS Pharma, Inc. (collectively, "NS") object to the portion of the Special Master's Order No. 2 (D.I. 254) (the "Order") denying NS's Motion to Compel Sarepta Therapeutics, Inc. ("Sarepta") to produce Sarepta's license agreements relating to Duchenne Muscular Dystrophy ("DMD") therapies beyond solely for the accused product Vyondys53®, and to produce an unredacted version of the Roche Agreement (Issue No. 1) and Order No. 3 denying additional redactions. The Special Master's decision to deny the majority of NS's Motion to Compel fails to adequately take into account the relevance of the requested documents and the broad discovery standards. The requested licensing agreements are key evidence of Sarepta's in- and out- licensing practices for the genetic medicine therapies for DMD at issue in this case—a relatively new commercial field with a limited licensing history. Specifically, this evidence goes to core damages issues in this case, and should be available the parties' technical and economic experts for evaluation.

Producing Sarepta's own license agreements limited to DMD therapies is proportional to the needs of the instant action—the requested agreements pertain to products that treat the same disease as the accused product by achieving the same goal (increasing dystrophin protein expression), involve the same type of technology (nucleic acid sequences to increase protein expression) as the accused product, and/or relate to a product that Sarepta expects will displace market need for the accused products. Accordingly, the Court should overrule the Special Master's Order insofar as it pertains to NS's Motion to Compel full production of these relevant license agreements and full unredaction of the Roche agreement's relevant terms.

I. Background

DMD is caused by mutations in the dystrophin gene, which codes for the muscle protein,

dystrophin. D.I. 86 ¶¶ 28-30. In DMD patients, the mutated dystrophin gene causes significant under-expression of dystrophin, leaving patients with insufficient levels of dystrophin to maintain their muscles. *Id.* But certain mutations can instead produce partially-functional dystrophin protein, which results in milder and slower disease progression. *Id.* ¶¶ 31-32.

DMD genetic medicine therapies seek to alleviate DMD symptoms by inducing a patient's cells to produce partially functional dystrophin, in effect mimicking a milder disease state. *Id.* ¶ 35. Antisense oligonucleotides ("ASOs") do this by delivering a short nucleic acid sequence that causes the cell to "skip" the mutated exon(s) when preparing the mRNA encoding for dystrophin (*id.* ¶ 34), while gene therapy delivers a nucleic acid sequence that encodes for a shortened version of dystrophin. *See* Appx44. NS and Sarepta each market exon skipping ASO DMD therapies. In this action, NS and Sarepta cross-assert patents relating to each's exon-skipping ASO products. *See* D.I. 86 ¶¶ 2-3, 11-12. Sarepta also recently received FDA approval for its DMD gene therapy product (which it expects to cannibalize sales of the accused ASO products), and Sarepta has second generation ASO products in development. *See* Appx14; Appx18-19.

The accused Sarepta product—Vyondys53—is one of four of Sarepta's marketed DMD treatments in its genetic medicine portfolio. Appx21. For DMD, Sarepta has three commercial first generation ASO products: Vyondys53 and two other ASO products (Exondys51® and Amondys45®), each of which is aimed at inducing skipping of a specific exon in dystrophin pre-mRNA. *See* Appx21. Sarepta also has three second generation AON products in development (PPMO53, PPMO 51, and PPMO 45) aimed at the same exons. Sarepta's gene therapy product ("SRP-9001" or Elevidys®) is not limited to any particular exon. Each of Sarepta's DMD products is marketed to the same patient population—DMD patients. The claimed benefit of each Sarepta DMD product is the same—to restore functional dystrophin. Appx23; Appx36. And Sarepta

characterizes the technology implemented in its products to be in the same class—precision genetic medicine.[1] Recent depositions of Sarepta witnesses have confirmed that Sarepta evaluates and [redacted]. *See* Appx.66; Appx69. In fact, Sarepta anticipates that [redacted]. Despite the relatedness of the therapies from a technically and economically, Sarepta has refused to produce licenses for any of its DMD products, aside from Vyondys53.

II. Procedural History

NS has requested relevant licenses from Sarepta that bear on damages issues from early on in this litigation. On March 11, 2022, NS served its first set of Requests for Production to Sarepta, which included, *inter alia*, a request for documents "reflecting royalty rates paid in the field, including by Sarepta, for technology related to ***treatments for Duchenne's Muscular Dystrophy or antisense oligonucleotides***."[2] *See* Appx83.[3] In response, Sarepta lodged boilerplate objections and stated that it would limit its production to only those documents "relating to licensing of ***Vyondys 53®***" on relevance and proportionality grounds. Appx83-84. Despite reasonable efforts to resolve the dispute regarding the scope of production in response to RFP No. 101, Sarepta refused to expand its production beyond licenses pertaining to the accused product. Given the parties' impasse, on June 15, 2023, NS filed its Motion to Compel seeking an order compelling

[1] Sarepta's product platform is a suite of four DMD genetic therapies: "Sarepta is pursuing the development of ***precision genetic medicine*** at the forefront of biotechnology for rare diseases: ***gene therapy, RNA-targeted exon skipping ASOs, and gene editing*** applied to three disease areas—***DMD***, Limb-girdle muscular dystrophy or Chacot-Marie-Tooth disease Type 1A." Appx298 https://www.sarepta.com/disease-areas (emphasis added). Note, NS is ***only*** seeking license agreement for DMD therapies and is ***not*** seeking licenses for Sarepta's other therapeutic categories (Limb-girdle muscular dystrophy or Chacot-Marie-Tooth disease Type 1A).

[2] Emphasis is added throughout unless noted otherwise.

[3] All "Appx" citations refer to pages in the Appendix filed contemporaneously herewith.

Sarepta to produce Sarepta's license agreements for ASO and DMD therapies beyond merely the accused product Vyondys53. *See* D.I. 247.

After briefing and oral argument regarding NS's Motion to Compel, the Special Master denied-in-part NS's Motion determining that RFP No. 101 and NS's request for licenses pertaining to ASO products and DMD therapies beyond the accused product were overbroad and not proportional to the needs of the instant action. *See* Order No. 2 (Appx6).

III. Legal Standard

"[T]he federal rules allow broad and liberal discovery." *Pacitti v. Macy's*, 193 F.3d 766, 777 (3d Cir. 1999). "For the purposes of discovery, relevancy is broadly construed." *Inventio AG v. ThyssenKrupp Elevator Am. Corp.*, 662 F. Supp. 2d 375, 380 (D. Del. 2009). "Generally, a party moving to compel discovery bears the burden of demonstrating the relevance of the requested information." *Delaware Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. No. 13-2108-RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016) (citation and internal quotation marks omitted). "Once relevance is shown, the party opposing discovery may show why discovery, even if relevant, should not be permitted." *Paoli v. Stetser*, C.A. No. 12-66-GMS-CJB, 2013 WL 2154393, at *3 (D. Del. May 16, 2013) (citation and internal quotation marks omitted).

"The Court reviews the Special Master's factual findings and legal conclusions de novo." *Cirba Inc. v. VMware, Inc.*, C.A. No. 19-742-LPS, 2022 WL 606655, at *1 (D. Del. Jan. 7, 2020).

IV. The Special Master's Ruling Should Be Overturned

A. The Special Master Failed to Apply the Rule 26 Standard for Discovery.

In his Order, the Special Master initially recognized the broad scope of discovery under Rule 26: "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense, and proportional to the needs of the case." Order at 3 (Appx3). Despite this recognition, the Special Master did not apply the broad standard of relevancy in assessing

whether Sarepta should be compelled to produce the requested agreements. Instead, the Special Master determined the requested licenses were "not commensurate with the scope of the claims and defenses." Order at Appx5. This was error. When the correct relevancy framework is applied, it is plain the requested licenses and Roche Agreement are relevant and should be produced.

The Special Master's foreclosing discovery at this stage of the case based on an erroneous understanding of the supposed "scope of claims an defenses" ignores that questions regarding "[t]he degree of comparability" are "factual issues best addressed by cross examination and not by exclusion." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012); *see also High Point SARL v. Sprint Nextel Corp.*, No. CIV.A. 09-2269-CM, 2012 WL 1533213, at *8 (D. Kan. Apr. 30, 2012) (compelling production of licenses and emphasizing that discovery standard is broader than ultimate admissibility, and discovery is not limited to just the "*most* relevant" comparable licenses). Ultimately, "[a] different standard exists for discoverability of other comparable patent licenses and the ultimate admissibility and weight to be given to the licenses at trial." *See Godo Kaisha IP Bridge 1 v. TCL Commcn's Tech. Holdings Ltd.*, Civ. A. No. 15-634-JFB-SRF, 2018 WL 6978576, at *2 (D. Del. Mar, 8, 2018). When the Special Master determined that the requested license agreements were not "commensurate" with the case scope, he foreclosed comparability arguments that are typically and properly reserved for experts. Indeed, under Federal Circuit law, "comparable licenses" are relevant to patent damages and need ***not*** address exactly the same technology as the asserted patents. *Id.* at *8; *see, e.g.*, *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1330 (Fed. Cir. 2014).

Licenses for DMD therapies that Sarepta itself believes will [redacted] and which Sarepta itself [redacted] are not so radically different from the accused product that discovery into these licenses should be precluded outright

at this phase. Courts routinely permit discovery into licenses pertaining to non-accused products and/or unasserted patents where, as here, there is a colorable claim of comparability. *See, e.g.*, *Godo*, 2018 WL 6978576, at *2 ("Comparable patents may be of assistance in determining a reasonable royalty rate."); *see also Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, No. 04 C 5312, 2007 WL 704525, at *2 (N.D. Ill. Mar. 1, 2007) (compelling production of licenses directed to other technologies but within the same industry as relevant to the second *Georgia Pacific* factor).

The Special Master's discovery ruling—which ignores the relevancy standard—wholly forecloses comparability arguments regarding the unproduced licenses and is significantly prejudicial to NS. Indeed, to deny discovery here merely on the basis that the non-accused products do not operate in precisely the same way or target the same exon as the accused product (*i.e.*, by skipping exon 53) would eviscerate the broad scope of discovery and unduly narrow the information that can be used in conducting a *Georgia Pacific* analysis. *Cf. Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1577 (Fed. Cir. 1995) ("[R]oyalty rates prevalent in the industry" are "relevant to determining a reasonable royalty" under *Georgia-Pacific* Factor 2, "rates paid by the licensee for the use of" comparable patents).

B. The Special Master Erroneously Found Production Was Not Consistent with the Parties' Prior Negotiations.

In declining to compel Sarepta to produce the requested license agreements and unredacted copy of the Roche Agreement, the Special Master relied, in part, on a misunderstanding of the parties' prior negotiations on these issues finding that NS had confirmed the scope of the dispute was limited to "all agreements/licenses related to exon-skipping oligonucleotides and/or Vyonds53." Order at Appx6. But the underlying correspondence reveals the opposite: NS never so limited its requests. To the contrary, NS continually pressed Sarepta for the very production it now seeks to compel. *See, e.g.*, Appx144 (reiterating request for "license agreements relating to

DMD-therapies beyond solely exon-skipping therapies (*e.g.*, Sarepta's licenses for SRP-9001, including an unredacted version of the Roche Agreement"); Appx137-138 (Sarepta requesting confirmation of NS's production of all "DMD-related licenses and agreements" because it wanted to confirm whether "NS itself has produced the kind of information [NS] seeks from Sarepta"). Based on this record evidence, it was error for the Special Master to find—and rely on as a basis for his decision—that NS has narrowed the scope of requested discovery to solely licenses relating to the accused product and exon-53 skipping therapies.

C. The Special Master's Lack of Proportionality Finding Is Flawed.

Despite Sarepta's own practice of [redacted], the Special Master declined to compel production of licensing agreements for these related products based, in part, on the supposed breadth of NS's request for production and purported lack of proportionality. Specifically, the Special Master denied NS's motion because it sought to have Sarepta produce "***all*** agreements and licenses relating to all DMD therapies regardless of whether they target exon 53 or exon-skipping therapies" and "***all*** of Sarepta's licenses relating to nucleic acid-based therapies known as AON regardless of whether they skip exons or treat DMD." D.I. 254 at 5. But production of these documents is proportional to the needs of the instant action—an action that involves accused DMD therapies. NS seeks to compel production of ***Sarepta's own*** licenses reflecting royalty rates paid in the field, including by Sarepta, for technology related to treatments for" DMD or ASO technology, and an unredacted copy of the Roche Agreement, which relates to [redacted] at issue in the case. *See* Appx83-86.

Sarepta never articulated any purported lack of proportionality aside from arguing that NS "seeks to obtain sensitive commercial information from Sarepta" about products not-at-issue in this case. But any supposed concerns regarding the sensitivity of information contained in the relevant license agreements is already resolved by the Stipulated Protective Order this Court

entered which provides protections from public disclosure for commercially sensitive information and also ensures that the parties' personnel cannot view information designated as outside counsel's eyes only. *See* D.I. 117 at 4. Insofar as Sarepta's concerns involve use at trial, "[a]ny problems with confidentiality can be resolved through a protective order and appropriate redactions." *Florida v. Abbott Labs.*, Civ. No. 08-155-SLR, 2009 WL 1764566, at *1 (D. Del. June 23, 2009); *see also Coca-Cola Bottling Co. v. Coca-Cola Co.*, 107 F.R.D. 288, 290 (D. Del. 1985) ("[e]xcept for a few privileged matters, nothing is sacred in civil litigation").

V. The Special Master's Lack of Relevancy Determination is Flawed.

Licenses for *all* DMD therapies—not solely the accused therapy in this case—are relevant because of the importance of understanding the relative value of technologies used in the treatment of DMD. Sarepta's own documents and statements confirm that license agreements pertaining to Sarepta's other DMD therapies (both types of nucleic acid therapies, ASO and gene therapies) are relevant to damages pertaining to the accused Vyondys53 product. Indeed, Sarepta's DMD products all share technical similarities including that they all fall within the area of "genetic medicine" (and more specifically nucleic acid based therapies) and aim to treat DMD patients by increases dystrophin production. Further, Sarepta's [redacted], and the [redacted], given DMD is a rare disease with a limited patient population. *See, e.g.*, Appx66; Appx69 (providing [redacted] for accused products and other products, with [redacted] for [redacted] redacted); Appx98 (Sikora Email (Mar. 9, 2023)) ("[D]ocuments produced in SRPT_VOL013 appear to provide [redacted] showing how Sarepta [redacted] in the [DMD] market, yet have extensive redactions that appear to withhold any information relating to these [redacted]."). Sarepta's Rule 30(b)(6) designee also recently confirmed that Sarepta

expects the "[redacted]" to "[redacted]," (Appx271:7-22), and that Sarepta has "[redacted]," *id.* at 274:23-275:1. Licenses pertaining to products which Sarepta [redacted], which treat the same disease, by the same therapeutic goal and target the same population are relevant to assessing the market for the accused product, and should be available for the parties' experts.

Further, the accused product in this action, Vyondys53, is not the sole product relevant to assessing potential damages. Indeed, under the well-established *Georgia Pacific* framework, various factors require consideration of licensing agreements beyond those for the accused product and asserted patents. *See, e.g.*, *Georgia Pacific* Factor 2 ("[t]he rates paid by the licensee for the use of ***other patents comparable*** to the patent in suit"); Factor 12 ("[t]he portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or ***analogous inventions***). Sarepta's licenses pertaining to its DMD therapies aside from the accused Vyondys53 product are relevant to these *Georgia Pacific* factors, and, thus, the Court should compel production of these licenses.

The Special Master undertook an *in camera* review of the admittedly relevant (Order No. 2 at p. 6-7) Sarepta-Roche license agreement, which [redacted]. Appx184-186, SRPT-VYDS-0204720 at 756-58 (Section 2.7.1 and Sections 2.7.4(a) and (d)). NS contends that Sarepta over-redacted the Roche agreement by obscuring the terms of the [redacted]. After review, the Special Master ordered Sarepta to unredact only a single excerpt from the defined

term "[redacted]" in the Roche agreement, Section 1.72. D.I. 263 (Order No. 3, p. 1), which confirmed that the [redacted], (Appx162, SRPT-VYDS-0204720 at 734).

In doing so, the Special Master erred by not also ordering Sarepta to unredact the pre-negotiated terms for the [redacted] and intellectual property relating thereto. This week, Sarepta's Rule 30(b)(6) witness on licensing, Mr. [redacted], confirmed that key financial terms about the license option [redacted] remained redacted. Appx285-286, [redacted] (Rough) Tr. at 207:20-208:6 (confirming that "[redacted]" applicable to exon skipping products had been redacted); *see also* Appx216, Roche LCA, SRPT-VYDS-0204720 at 788 (redacted [redacted] for exon-skipping products), at Appx219 (royalty rate for "[redacted]" other than the "[redacted]," *e.g.*, for e[redacted]). [redacted] likewise confirmed he was unaware of any agreements, other than the Roche agreement, whereby Sarepta had [redacted] the UWA patents. Appx291, [redacted] (Rough) Tr. at 213:21-214:1. The terms of exon-skipping license contemplated by the Roche agreement thus are relevant to a least a hypothetical negotiation involving Sarepta's asserted UWA Patents—according to Sarepta's corporate representative, the Roche agreement is the only instance in which Sarepta agreed to a set of terms by which it was willing to sublicense rights it held to the UWA patent family.

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For these reasons, the Court should overrule the Special Master's denial of NS's Motion to Compel with respect to production of license agreements for AON and DMD therapies beyond merely the accused product Vyondys53, and compel Sarepta to produce these relevant license agreements.

Dated: July 27, 2023

Respectfully submitted,

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